

ARTICLE 61-02

PHARMACIES

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CHAPTER 61-02-01 PHARMACY PERMITS

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61-02-01-01. Permit required. No person, partnership, association, or corporation shall conduct a pharmacy in North Dakota without first obtaining a permit to do so from the board. A fee, set by the board but not to exceed that prescribed by statute, shall be charged for each permit.

1. Each physical location of a pharmacy shall have a separate pharmacy permit. A location is defined as being in the same building at the same physical address. Buildings connected by tunnels, skywalks, or other similar methods must be deemed separate physical locations.
2. Any pharmacy receiving a permit shall advise the board, when applying for the permit and when changes occur, of the name of the employees of the pharmacy who are:

- a. The pharmacist-in-charge of the pharmacy, who shall be a licensed pharmacist in North Dakota in good standing;
 - b. All other licensed pharmacists who shall be licensed pharmacists in North Dakota in good standing;
 - c. All licensed pharmacy interns who shall be licensed pharmacy interns in North Dakota in good standing;
 - d. All registered pharmacy technicians who shall be registered pharmacy technicians in North Dakota in good standing; and
 - e. All supportive personnel permitted in the pharmacy area.
3. Nothing in this section prohibits a pharmacy with other than class F permit from delivering drugs or devices through the United States postal service or other parcel delivery service or hand delivery.
4. Classes of pharmacy permits are as follows:
 - a. Class A - Permit to conduct an outpatient pharmacy. These permits are issued to a pharmacy dispensing drugs or devices to the general public pursuant to a valid prescription.
 - b. Class B - Permit to conduct a hospital pharmacy. These permits are issued to a pharmacy dispensing drugs or devices to persons who are patients in a hospital, patients who are being discharged, or patients in emergency situations, pursuant to a valid prescription. These permits shall be issued to facilities licensed under North Dakota Century Code chapter 23-16 and shall be issued in the name of the facility.
 - c. Class C - Permit to conduct a home health care pharmacy. These permits are issued to a pharmacy dispensing sterile injectable drug products and devices to the general public who are not patients within a facility with a class B pharmacy permit pursuant to a valid prescription.
 - d. Class D - Permit to conduct a long-term care pharmacy. These permits are issued to a pharmacy dispensing drugs and devices to residents of facilities licensed under North Dakota Century Code chapters 23-09.3 and 23-16 pursuant to a valid prescription which are not physically accessed by the general public.
 - e. Class E - Permit to conduct a nuclear pharmacy. These permits are issued to a pharmacy dispensing or providing diagnostic or therapeutic radioactive drugs or devices for administration to an ultimate user.

- f. Class F - Permit to conduct a mail-order pharmacy. These permits are issued to a pharmacy dispensing drugs and devices to the general public exclusively through the United States postal service or other parcel delivery service pursuant to a valid prescription but which are not physically accessed by the general public.
 - g. Class G - Permit to conduct an out-of-state pharmacy. These permits are issued to any pharmacy operating outside the state of North Dakota which ships, mails, or delivers in any manner a dispensed prescription drug or legend device into North Dakota, which shall obtain and hold a pharmacy permit issued by the North Dakota state board of pharmacy and that part of the pharmacy operation dispensing the prescription for a North Dakota resident shall abide by state laws and rules of the board.
 - h. Class H - Permit to conduct a governmental agency pharmacy. This permit is issued to a pharmacy operated by the state of North Dakota, dispensing drugs and devices only to patients within correctional facilities or rehabilitation facilities, or for the purpose of teaching at institutions of higher learning, pursuant to a valid prescription.
 - i. Class I - Permit to conduct a research pharmacy. This permit is issued to a pharmacy in which scientific research is conducted under protocols established by an institutional review board meeting federal drug administration guidelines. Pharmaceuticals on hand are incident to the research being conducted. Security and storage for pharmaceuticals must meet United States Pharmacopeia and board of pharmacy requirements. A specific application for a pharmacy permit must be made delineating the specific physical facility to be utilized.
 - j. Class J - Permit to conduct an office practice pharmacy. Any licensed pharmacist may practice in an office pharmacy setting where prescriptions are not routinely dispensed. If legend drugs or devices are maintained, a permit must be obtained by making application to the board of pharmacy delineating specific practice intentions and assuring the board that security and storage requirements are met for any legend drugs or pharmaceuticals on hand.
 - k. Class K - Permit to conduct telepharmacy. A pharmacy staffed by a registered pharmacy technician with access to its main pharmacy and registered pharmacists by computer link, videolink, and audiolink while open.
5. Any applicable rule governing the practice of pharmacy shall apply to all permits under this section.

6. Operating in one class does not preclude permitting in another class. Pharmacies wishing to operate in more than one class shall apply on forms prescribed by the board, pay a fee set by the board, and comply with all rules for each class.

History: Effective October 1, 1999; amended effective January 1, 2004.

General Authority: NDCC 43-15-34

Law Implemented: NDCC 43-15-34

61-02-01-02. Application for permit. Applications for permits and renewal of permits to conduct a pharmacy or drugstore shall be made in writing on such form or forms as the board may from time to time prescribe, and shall set forth information required by the board to enable it to determine if the pharmacy or drugstore will be conducted in full compliance with existing laws and with regulations established thereunder by the board of pharmacy. This information shall include:

1. Name and address of proposed pharmacy.
2. Name of current owner.
3. If applicant is a sole proprietor, evidence that owner is a registered pharmacist in good standing.
4. If applicant is a partnership, evidence that each active partner is a registered pharmacist in good standing, names of all partners and ownership interests of each, and copy of partnership agreement.
5. If applicant is a corporation, names of corporate officers, list of shareholders and shares of stock held by each, affidavit of stock ownership showing that a majority of the stock is owned by registered pharmacists in good standing, actively and regularly employed in and responsible for the management, supervision, and operation of applicant pharmacy, copies where applicable of agreement to form corporation, articles of incorporation, certificate of incorporation, bylaws, employment agreements, financial records as they may pertain to stock ownership requirements, and any other corporate documents relating to ownership or control of applicant pharmacy or corporation, or both.
6. Leases on space to be occupied by applicant or permitholder.
7. Blueprints or drawings of floor plans and physical layout of pharmacy and space to be occupied by applicant.
8. Franchise or license agreements where applicable.
9. Names of registered pharmacists employed.
10. Name of pharmacist in charge.

11. Information showing that adequate technical equipment is maintained.

Documents to be provided herein shall include all changes and amendments. All changes and amendments in documents previously furnished to the board shall be promptly submitted to the board. An application for a renewal of a permit need not include documents previously furnished to the board except where the facts, information, or documents have been changed or amended and not previously furnished to the board. The board shall have the right to require that an applicant or permit holder furnish to the board current documents required hereunder, including all changes or amendments, at any time.

History: Amended effective August 1, 1983.

General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-34, 43-15-35

Law Implemented: NDCC 28-32-03, 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-34, 43-15-35

61-02-01-03. Pharmaceutical compounding standards. The minimum standards and technical equipment to be considered as adequate shall include:

1. Suitable storage facilities.
2. Scales or balances appropriate for the compounding done in the pharmacy.
3. Suitable area of the pharmacy used for compounding activities.
4. Suitable heating apparatus.
5. Logbook or record system to track each compounded prescription and the components used.
6. Record book containing formulas with directions for compounding.
7. A policy and procedure manual is required. Policies and procedures must be in place pertinent to the level of volume and complexity of the compounding operation of the practice.
8. Poison record book and suitable prescription files.
9. Suitable current reference sources either in book or electronic data form (available in the pharmacy or on-line) which might include the United States Pharmacopeia and National Formulary, the United States Pharmacopeia Dispensing Information, Facts & Comparisons, Micro Medex, the ASHP Formulary, or other suitable references determined by the board which are pertinent to the practice carried on in the licensed pharmacy.

10. A reasonable amount of consumable material, such as filter paper, powder papers, litmus paper, empty capsules, ointment jars, bottles, vials, safety closures, powder boxes, labels, and distilled water.
11. It is acceptable to compound drug products to be used by practitioners in their office for administration to patients. These products cannot be dispensed or sold to others. Sales to other pharmacies, clinics, or hospitals are manufacturing and are not allowed.

The board of pharmacy recognizes that the equipment needed will depend on the type of pharmaceutical services offered, and therefore, variations for required equipment may be granted by the board of pharmacy.

History: Amended effective August 1, 1983; April 1, 1988; October 1, 1999; December 1, 2003.

General Authority: NDCC 28-32-02, 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-35(2), 43-15-35(3), 43-15-36

Law Implemented: NDCC 28-32-03, 43-15-10(9), 43-15-10(12), 43-15-10(14), 43-15-35(2), 43-15-35(3), 43-15-36

61-02-01-04. Permit not transferable. A permit registers the pharmacy to which it is issued at the location specified in the permit, and is not transferable. It is issued on the application of the owner, or the registered pharmacist in charge, on the sworn statement that the pharmacy will be conducted in accordance with the provisions of law. If it is desired to operate, maintain, open, or establish more than one pharmacy, separate applications shall be made and separate permits issued for each.

General Authority: NDCC 43-15-10(9), 43-15-34, 43-15-39

Law Implemented: NDCC 43-15-10(9), 43-15-34, 43-15-39

61-02-01-05. Change of ownership. When a pharmacy changes ownership, the original permit becomes void and must be surrendered to the board, and a new permit secured by the new owner or owners. This is required even in case there is no change in the name of the pharmacy or in the registered pharmacist in charge of the pharmacy. The board shall be promptly notified of any change in ownership of a pharmacy. In the case of a corporation holding a pharmacy permit, the board shall be immediately notified at any time when a majority of the stock is not owned by registered pharmacists in good standing, actively and regularly employed in and responsible for the management, supervision, and operation of the pharmacy. In the case of a partnership holding a pharmacy permit, the board shall be notified as to the addition or removal of one or more partners in the partnership.

General Authority: NDCC 43-15-10(9), 43-15-35(5)

Law Implemented: NDCC 43-15-10(9), 43-15-35(5)

61-02-01-06. Affidavit of ownership. An affidavit shall be filed each year with the application for renewal of a pharmacy permit, indicating in the case of a

partnership, that each active member is a registered pharmacist, or in the case of a corporation, that the majority stock is owned by registered pharmacists in good standing, actively and regularly employed in and responsible for the management, supervision, and operation of the pharmacy.

General Authority: NDCC 43-15-10(9), 43-15-35(5)

Law Implemented: NDCC 43-15-10(9), 43-15-35(5)

61-02-01-07. Renewal of permits. Each pharmacy permit shall expire on June thirtieth of each year, and shall be renewed annually by filing an application therefor, on or before June first of each year, together with a fee set by the board, but not to exceed that prescribed by statute.

General Authority: NDCC 43-15-10(9), 43-15-38

Law Implemented: NDCC 43-15-10(9), 43-15-38

61-02-01-08. Change of location. Before a pharmacy changes the location of its business, it shall first submit to the board a new application for a permit, setting forth such changes, and shall submit therewith the information and documents required in an initial application for a permit. If the board approves the application, no additional fee shall be made for the new permit.

General Authority: NDCC 43-15-10(9), 43-15-10(11)

Law Implemented: NDCC 43-15-10(9), 43-15-10(11)

61-02-01-09. Permit for heirs at law of pharmacist. The issuance of a permit to the heirs at law of a pharmacist shall not be refused on the grounds that such heirs at law are not registered pharmacists, provided assurance will be given that when the pharmacy is disposed of by the heirs at law of the registered pharmacist owner, it shall be sold only to a registered pharmacist or a corporation or partnership controlled by a registered pharmacist in North Dakota.

General Authority: NDCC 43-15-11(9)

Law Implemented: NDCC 43-15-11(9)

61-02-01-10. Pharmacist-in-charge - Requirement - Definition - Duties. No permitholder shall conduct a pharmacy without a pharmacist-in-charge who shall be designated in the application for a pharmacy permit and each renewal of pharmacy permit. The term "pharmacist-in-charge" means a duly licensed pharmacist in North Dakota who has been so designated, and it shall be the pharmacist's duty and responsibility consistent with the accepted standards of professional conduct and practice and in compliance with all applicable laws and regulations to:

1. Establish for the employees of the pharmacy policies and procedures for the procurement, storage, compounding, and dispensing of drugs.
2. Supervise all of the professional employees of the pharmacy.

3. Supervise all of the nonprofessional employees of the pharmacy insofar as their duties relate to the sale or storage, or both, of drugs.
4. Establish and supervise the recordkeeping system for the purchase, sale, possession, storage, safekeeping, and return of drugs.
5. Notify the board immediately upon the pharmacist's knowledge that the pharmacist's services as pharmacist-in-charge have been or will be terminated.

General Authority: NDCC 43-15-10(9), 43-15-35(4)

Law Implemented: NDCC 43-15-10(9), 43-15-35(4)

61-02-01-11. Pharmacist-in-charge - Termination of service. Each pharmacy shall notify the board of pharmacy immediately upon knowledge of the termination of the services of the pharmacist-in-charge and further, shall immediately designate a successor pharmacist-in-charge and immediately notify the board of pharmacy of such designation. The board of pharmacy upon receiving such notice shall furnish the successor pharmacist-in-charge such form or forms as it may from time to time prescribe which form or forms must be completed by the successor pharmacist-in-charge and filed with the board within ten days after receipt.

General Authority: NDCC 43-15-10(9), 43-15-35(4)

Law Implemented: NDCC 43-15-10(9), 43-15-35(4)

61-02-01-12. Posting of permit. Each pharmacy permit shall be posted and exposed in a conspicuous place in the pharmacy for which the permit has been issued.

General Authority: NDCC 43-15-10(9), 43-15-39

Law Implemented: NDCC 43-15-10(9), 43-15-39

61-02-01-13. Pharmacist on duty. Each pharmacy shall have at least one registered pharmacist on duty and physically present in the pharmacy area at all times that the prescription area is open for the transaction of business.

History: Amended effective May 1, 1984.

General Authority: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

Law Implemented: NDCC 43-15-10(9), 43-15-10(12), 43-15-10(14)

61-02-01-14. Limitation on rent. Before a pharmacy permit is issued, in the case of a pharmacy leasing space, a copy of the lease agreement must be furnished to the board which must include rental terms and information. The lease rental amounts, less in-house sales and wholesale sales, may not exceed five percent of the total gross sales of the pharmacy, with the further provision that the landlord shall furnish all utilities including heat, electrical, and janitorial services, but not including telephone service. The board recognizes that the lease terms and rent

will depend on the type of pharmaceutical services offered, and therefore, variations for rent may be granted by the board of pharmacy.

History: Effective April 1, 1988; amended effective July 1, 1996.

General Authority: NDCC 28-32-02, 43-15-10(7)(9)(12)(14), 43-15-34, 43-15-35, 43-15-36

Law Implemented: NDCC 28-32-03